Clinical Criteria for Hepatitis C (HCV) Therapy

Pre-Treatment Evaluation

- Must have chronic hepatitis C and HCV genotype and sub-genotype documented;
- HCV RNA quantitative within 90 days of application for therapy;
- Liver biopsy or other accepted test (Appendix A) demonstrating liver fibrosis corresponding to Metavir score of greater than or equal to 2;
- Previous HCV treatment history and outcome;
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression;
- Adherence evaluation: Providers must assess and document the patient's ability to adhere to therapy;
- Drug resistance testing as indicated; and
- Women of child-bearing age who are prescribed a ribavirin-containing regimen must have documentation of a negative pregnancy test

Patient Treatment Plan

- It is required that the patient have a treatment plan developed by, or in collaboration with, a provider with expertise in Hepatitis C management. Sample treatment plan documents are available for use.
- If the patient or their partner is of childbearing age, at least two (2) forms of contraception must be used (by the patient or their partner) if a RBV -containing regimen is prescribed throughout the duration of therapy and for 6 months after the regimen is completed.

Drug Therapy

- Must be in accordance with FDA approved indications.

Treatment Options[1]:

Genotype 1a:

- **Daclatasvir (Daklinza®) and Sofosbuvir (Sovaldi®)[2]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks

Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

- **Elbasvir/grazoprevir (Zepatier™)[3]**
  - Prior to requesting/initiating therapy with this agent, genotype testing for baseline NS5A polymorphisms is REQUIRED, in order to determine treatment length.
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment	Treatment length
Treatment naïve, without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment naïve, with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks
Treatment experienced (PegIFN/RBV), without baseline NS5A polymorphisms	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV), with baseline NS5A polymorphisms	Zepatier + weight based ribavirin	16 weeks

- **Ledipasvir/sofosbuvir (Harvoni®)[4]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naive patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.

**A 12 week regimen with weight-based ribavirin may be considered.

- **Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak®) with Weight Based Ribavirin[5]**
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis	24 weeks

- **Simeprevir (Olysio®) and Sofosbuvir (Sovaldi®)[5]**
  - Negative Q80K polymorphism test REQUIRED.
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

Genotype 1b:

- **Daclatasvir (Daklinza®) and Sofosbuvir (Sovaldi®)[2]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

- **Elbasvir/grazoprevir (Zepatier™)[3]**
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve	12 weeks
Treatment experienced (PegIFN/RBV)	12 weeks

- **Ledipasvir/sofosbuvir (Harvoni®)[4]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis*	12 weeks
Treatment naïve, with cirrhosis	12 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis**	24 weeks

*8 weeks of treatment can be considered in treatment naive patients without cirrhosis who have pretreatment HCV RNA levels less than 6 million IU/mL.
**A 12 week regimen with weight-based ribavirin may be considered.

- **Paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak®)[5]**
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis*	12 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

- **Simeprevir (Olysio®) and Sofosbuvir (Sovaldi®)[6]**
  - Negative Q80K polymorphism test REQUIRED.
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced, with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen for the same treatment length.

Genotype 2:

- **Sofosbuvir (Sovaldi®) and weight based ribavirin[7]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis	16 weeks
Treatment experienced, without cirrhosis*	16 weeks
Treatment experienced, with cirrhosis**	16 weeks

*Providers may add PegIFN to this regimen to shorten treatment length to 12 weeks.
**Providers may request and extension to 24 weeks if medically necessary.

Genotype 3:

- **Daclatasvir (Dacklinza®) and Sofosbuvir (Sovaldi®)[2]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, without cirrhosis	12 weeks
Treatment naïve, with cirrhosis*	24 weeks
Treatment experienced, without cirrhosis	12 weeks
Treatment experienced with cirrhosis*	24 weeks

*Providers may add weight-based ribavirin to this regimen with the same treatment length.

- **Sofosbuvir (Sovaldi®) and weight based ribavirin and PegIFN[7]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis*	12 weeks
Treatment experienced, with our without cirrhosis	12 weeks

*Providers may use this regimen without PegIFN in patients who are IFN ineligible for a treatment length of 24 weeks.

Genotype 4:

- **Elbasvir/grazoprevir (Zepatier™)[3]**
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment	Treatment length
Treatment naïve	Zepatier	12 weeks
Treatment experienced (PegIFN/RBV)	Zepatier + weight based ribavirin	16 weeks

- **Ledipasvir/sofosbuvir (Harvoni®)[4]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

- **Ombitasvir/paritaprevir/ritonavir (Technivie®) and weight based ribavirin[8]**
  - Prior to requesting/initiating therapy with this agent in a patient with cirrhosis (stage F4 by Metavir), documentation of Child-Pugh status of A is required.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

- **Sofosbuvir (Sovaldi®) and weight based ribavirin [7]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis*	24 weeks
Treatment naïve with or without cirrhosis	24 weeks
Treatment experienced with or without cirrhosis*	24 weeks

*****Providers may add PegIFN to this regimen for a treatment length of 12 weeks.

Genotype 5 and 6:

- **Ledipasvir/sofosbuvir (Harvoni®)[4]**
  - Prior to requesting/initiating therapy with this agent, documentation of eGFR ≥30 mL/min is required for approval.

Patient characteristics	Treatment length
Treatment naïve, with or without cirrhosis	12 weeks
Treatment experienced, with or without cirrhosis	12 weeks

References:

1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. February 8, 2016 accessed.
2. Daklinza [package insert]. Princeton, NJ: Bristol-Myers Squibb Company, February 2016.
3. Zepatier [package insert]. Whitehouse Station, NJ: Merck and Co., Inc., January 2016.
4. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2015.
5. Viekira pak [package insert]. North Chicago, IL: AbbVie Inc., January 2016.
6. Olysio [package insert]. NJ: Janssen Therapeutics, October 2015.
7. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc., August 2015.
8. Technivie [package insert]. North Chicago, IL: AbbVie Inc., January 2016.

Appendix A: Acceptable tests for determination of fibrosis in HCV

Noninvasive methods for determination of liver disease

Numerous noninvasive methodologies have been developed to determine the degree of fibrosis in patients infected with chronic HCV. These methodologies employ either the use of biomarkers or evaluation of liver stiffness to make a determination regarding the degree of liver fibrosis.[1] Below is a table of acceptable noninvasive testing and the score which is equivalent to metavir stage F2.

Noninvasive test	Score equivalent to metavir stage F2
FibroScan (transient elastography)	7.1 kPa[2]
Point shear wave elastography (pSWE) Acoustic radiation force impulse imaging (AFRI)	1.34 m/s[3]
MR elastography	3.66 kPa[4]
Hepascore ®/Fibroscore ®	0.2
Fibrosure®	0.48

1. Castera L. Noninvasive methods to assess liver disease in patients with hepatitis B or C. Gastroenterology 2012;142:1293-1302.
2. Foucher J, Chanteloup E, Vergniol J, et al. Diagnosis of cirrhosis by transient elastography (Fibroscan): a prospective study. Gut 2006;55:403-8.
3. Ferraioli G, Tinelli C, Dal Bello B, et al. Accuracy of real-time shear wave elastography for assessing liver fibrosis in chronic hepatitis C: a pilot study. Hepatology 2012;56:2125.
4. Singh S, Venkatesh SK, Wang Z, et al. Diagnostic performance of magnetic resonance elastography in staging liver fibrosis: a systematic review and meta-analysis of individual participant data. Clin Gastroenterol Hepatol 2015;13:440.